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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,450	12/05/2003	Christina Khoo	7129-00	1031

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EXAMINER	
FORD, ALLISON M	
ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/729,450	KHOO ET AL.	
	Examiner	Art Unit	
	Allison M. Ford	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

Claims 1-14 are pending in the current application.

Response to Arguments & Amendments

Applicant's amendments to claims 1 and 4-14 in the response filed 2/22/05 have been entered. Applicant's arguments have been considered, but are not found persuasive.

Specification

Applicants have amended the title of the invention to read: COMPOSITION AND METHOD FOR REDUCING DIARRHEA IN A MAMMAL. The amendment has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Applicant's amendments to claims 1 and 4-14 have been entered and obviate the rejections under 35 USC § 112, second paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Applicant's amendment to claims 1 and 14 obviate the rejections under 35 USC § 102(b) over Shields, Jr et al and Chandler.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-14 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Shields, Jr. et al (US Patent 6,156,355), in view of Wadsworth et al (US Patent 6,737,089), and Klimberg et al (*Arch Surg*, 1990).

Shields, Jr. et al teach a dog food composition, 'The Herding Diet' which comprises fermentable fibers, in the amount of 4.0%; omega-3 fatty acids, in the amount of 0.2%; antioxidants; and glutamine (See col. 9, ln 48-51; col. 11, ln 25-38 & 53-54; col. 12, ln 11-15; col. 23, ln 4-14 & 'Analysis'). The 'Herding Diet' is specially formulated for dogs that are prone to chronic GI inflammation and diarrhea; it is designed to be fed to dogs as a means of controlling GI inflammation and diarrhea (See col. 11, ln 18-28). Shields, Jr. et al teach that the glutamine is the primary source of fuel for the cells for the intestinal tract, and it is beneficial in stress situations (such as times of gastrointestinal stress), in particular it is beneficial to cells of the immune system of the intestinal tract (See col. 12, ln 11-22); however, they do not disclose a precise amount of glutamine to include in the diet.

Wadsworth et al and Klimberg et al both provide similar teachings on the benefits of glutamine on intestinal health during times of gastrointestinal stress (such as bouts of diarrhea). Wadsworth et al teach glutamine, 5-10% wt, as an additive to animal's diets, specifically dog and cat diets, can provide improved digestive system support (See Wadsworth et al, col. 7, ln 51-60 and col. 13, ln 34-49 (Example

4)). Klimberg et al teach adding glutamine, 3% wt, to diets of rats suffering gastrointestinal distress from abdominal radiation, diminished bloody diarrhea and reduced the incidence of bowel perforation (See Klimberg et al, Pg 1040, col. 2- Pg. 1041, col. 2).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use the amounts of glutamine specified by either Wadsworth et al or Klimberg et al (5-10% and 3%, respectively) in the diet disclosed by Shields, Jr. et al. Shields, Jr. et al already teach using glutamine in the diet in order to treat stressed GI tracts, however because they do not teach a specific amount of glutamine, one of ordinary skill in the art would have been motivated to use the amounts of glutamine taught by Wadsworth et al and Klimberg et al. One would expect success because all three teach that glutamine treats stressed GI tracts by providing the essential fuel for intestinal immune cells (See, e.g. Shields, Jr. et al, col. 12, ln 11-22). Though Klimberg et al uses rats as the experimental animal, it would have been obvious to extend the results to include dogs, as described by Shields, Jr et al, because they are both mammals, both have simple digestive tracts, and it is known that glutamine has similar affects on both, it is simply the amount of glutamine that is extrapolated. For the same reasons it would be obvious to extend the results of Shields, Jr. et al, in view of Klimberg et al, to include cats; therefore, a diet of the same composition, including glutamine, fermentable fiber, omega-3 fatty acids, and antioxidants in the specified amounts would be obvious for cats as well as dogs.

Shields, Jr. et al does teach the importance of antioxidants as scavengers of oxygen, and terminators of free radicals, and therefore their inclusion in the diet (col. 5, ln 65- col. 6, ln 11). Shields, Jr. et al, however, do not teach a specific amount of antioxidants present in the diet. Wadsworth et al also teach inclusion of vitamins and antioxidants, such as vitamins A and E, in amounts from 0-10% by weight (See col. 5, ln 24-42). However, any pharmaceutical amount would be appropriate for these diets. Excess vitamins are flushed from the system; therefore, it would be obvious to include any amount of antioxidants, within a pharmaceutically accepted range, with expectations of the benefits and without

concern of over dosage. Therefore, though Shields, Jr et al is silent on the amount of antioxidants in their diet, it would have been obvious to include any amount within a pharmaceutical range, such as 0.1-3% by weight (Claims 6, 9, 11, & 13).

Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chandler (*In Practice*, 2002).

Chandler teaches diets for dogs and cats for the treatment and control of gastrointestinal diseases, which result in symptoms such as diarrhea. Chandler et al teach that a diet, which includes fermentable fibers, omega-3 fatty acids, antioxidants, and glutamine, can benefit an animal with a stressed gastrointestinal tract (See Pg. 529, col. 2, and especially Pg. 533, col. 1) (Claims 1-3). Chandler teaches a diet comprising these ingredients can be used as a treatment for gastrointestinal diseases (See especially Pg. 533) (Claim 14).

Though Chandler is silent on the precise amounts of glutamine, fermentable fibers, omega-3 fatty acids, and antioxidants, it would have been obvious to a person of ordinary skill in the art to experiment with varying amounts, within pharmaceutical ranges, of each ingredient to optimize the treatment potential of the diet. Chandler teach that each specific ingredient plays an important role in maintaining and, in times of stress restoring gastrointestinal health (See especially, Pg. 529, col. 1- Pg. 531, col. 1). A person of ordinary skill in the art would have been motivated to increase the amount of fermentable fiber, omega-3 fatty acids, and antioxidants, and to include glutamine in a diet for a dog or cat with GI tract problems because these ingredients are highly digestible, the fiber promotes fecal bulk, the omega-3 fatty acids help to decrease inflammation, antioxidants promote immune response, and need to be replaced during bouts of diarrhea due to being flushed out, and glutamine has been found to provide energy for

enterocytes during times of stress, boosting immune ability and GI health (See Chandler Pg. 529, col. 2- Pg. 533, col. 1). One would have expected success because Chandler describes a diet containing these ingredients as a means for treating GI problems (See Chandler Pg. 529, col. 2- Pg. 533, col. 1). Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Applicant argues that the 'Herding Diet' formulation taught by Shields, Jr et al, nor the formulations taught by Wadsworth et al or Klimberg et al teach, by themselves, all the limitations of amended claims 1 and 14, nor is there motivation to combine the teachings.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by referring to references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the combined teachings of Shields, Jr et al and Wadsworth et al and Klimberg et al do teach all the limitations of amended claims 1 and 14, and the dependent claims 2-13, and the examiner maintains that there is motivation to combine the references.

Shields, Jr et al's 'Herding Diet' is specifically formulated for breeds prone to chronic GI inflammation and diarrhea; each component of the diet plays a specific role in preventing or ameliorating bouts of GI inflammation and diarrhea. Glutamine is the primary source of fuel for the cells for the

intestinal tract, and it is beneficial in stress situations (such as times of gastrointestinal stress), in particular it is beneficial to cells of the immune system of the intestinal tract (See col. 12, ln 11-22). Antioxidants act as scavengers of oxygen, and terminators of free radicals, and are therefore included in the diet (col. 5, ln 65- col. 6, ln 11). Because both glutamine and antioxidants are taught to have specific beneficial properties in preventing or ameliorating GI inflammation and diarrhea one of ordinary skill in the art would have been motivated to use any pharmaceutically acceptable amount. Specific amounts glutamine effective to treat GI inflammation and diarrhea are disclosed by Wadsworth et al and Klimberg et al. Klimberg et al specifically teach a diet comprising 3% glutamine diminished diarrhea caused by abdominal radiation; Wadsworth et al specifically teaches a diet comprising 5-10% glutamine improved digestive system support. Therefore, because Wadsworth et al and Klimberg et al teach a diet comprising 3-10% (w/w) glutamine is effective in improving the digestive system and diminishing diarrhea, one of ordinary skill in the art would be motivated to provide approximately 3-5% (w/w) glutamine in the 'Herding Diet' of Shields, Jr et al. Additionally, Wadsworth et al teach inclusion of vitamins and antioxidants, such as vitamins A and E, in amounts from 0-10% by weight (See col. 5, ln 24-42). Because Shields, Jr et al teach beneficial effects of antioxidants in the disclosed diet, but no specific amount, one would have been motivated to use the amount of antioxidants taught by Wadsworth, knowing that excess vitamins are flushed from the system, it would have been obvious to include any amount within a pharmaceutical range, such as 0.1-3% by weight. Therefore, the 'Herding Diet' of Shields, Jr., comprising the specific amounts of glutamine and antioxidants taught by Wadsworth et al and Klimberg et al, does include the specific amounts of glutamine, fermentable fiber, antioxidants, and omega-3-fatty acids claimed in the current application.

Similarly, in response to applicant's arguments that Chandler does not provide specific teachings on the amounts of fermentable fibers, omega-3 fatty acids, antioxidants, and glutamine to be included in

the diet that is intended to be used as a treatment for gastrointestinal diseases, examiner maintains that the specific amounts can be routinely optimized by one of ordinary skill in the art without undue experimentation. Chandler teaches the specific benefits of each ingredient in treating GI inflammation; therefore one of ordinary skill in the art would have been motivated to include each of the ingredients in substantial amounts, comprising, at least, 0.1% of omega-3 fatty acids, antioxidants, and glutamine, and at least 0.5% of fermentable fibers.

In response to applicant's arguments that one would not be motivated to combine references that teach the individual benefits of glutamine, antioxidants, omega-3-fatty acids, and fermentable fiber, the examiner points out that combining two different compositions that have the same effect to make a third composition with the same effect as the first two is prima facie obvious. See *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Therefore, combining two or more separate ingredients that each, individually, have been shown to benefit the digestive tract and/or ameliorate symptoms of GI inflammation, such as diarrhea, to make a composition for the purpose of benefiting the digestive tract and/or ameliorating symptoms of GI inflammation such as diarrhea, is prima facie obvious.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Allison M Ford
Examiner
Art Unit 1651

LEON B. LANKFORD, JR.
PRIMARY EXAMINER